



March 14, 2023

Double Medical Technology Inc.  
Yan Zuo  
International RA Supervisor  
No. 18, Shanbianhong East Road, Haicang District  
Xiamen, Fujian 361026  
China

Re: K223753

Trade/Device Name: Cervical Plate System  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal Intervertebral Body Fixation Orthosis  
Regulatory Class: Class II  
Product Code: KWQ  
Dated: December 8, 2022  
Received: December 14, 2022

Dear Yan Zuo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin  
O'Neill -S 

Colin O'Neill, M.B.E.  
Assistant Director  
DHT6B: Division of Spinal Devices  
OHT6: Office of Orthopedic Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K223753

Device Name  
Cervical Plate System

### Indications for Use (Describe)

Cervical Plate System is intended for anterior interbody screw fixation from C2 to T1 and is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with:

- 1)degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
- 2)trauma (including fractures);
- 3)tumors;
- 4)deformity(defined as kyphosis, lordosis,or scoliosis);
- 5)pseudoarthrosis;
- 6)failed previous fusions

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## K223753- 510(k) Summary

5.1 Submitter	
<b>Name</b>	Double Medical Technology Inc.
<b>Address</b>	No. 18, Shanbianhong East Road, Haicang District, Xiamen, 361026, P. R. China
<b>Phone</b>	+86 592 6885079
<b>Contact person</b>	Yan Zuo
<b>Date prepared</b>	March 10th, 2023
5.2 Proposed Device	
<b>Trade/proprietary name</b>	Cervical Plate System
<b>Common or usual name</b>	Cervical Plate System
<b>Classification name</b>	Spinal Intervertebral Body Fixation Orthosis
<b>Regulation number</b>	21 CFR 888.3060
<b>Product code</b>	KQW
<b>Regulatory class</b>	II
<b>Classification panel</b>	Orthopedic
5.3 Predicate Device	
<b>Legally marketed device(s) to which equivalence is claimed</b>	<b>Primary predicate device:</b> K141632 ZEVO™ Anterior Cervical Plate System
<b>Reason for 510(k) submission</b>	New device(Implant)

### 5.4 Device Description

Cervical Plate System consist of anterior cervical spine plate II, anterior cervical spine plate IV and screws. The anterior cervical spine plate is fixed to the front of the cervical vertebrae by screws to play an auxiliary role in maintaining the stability of the surgical segment and preventing the fusion implant from coming out. Screws are available for fixed angle or variable angle implantation.

Bone plates in Cervical Plate System are made of unalloyed titanium following ASTM F67 and titanium alloy following ASTM F1472 as well as ASTM F1295, and bone screws in Cervical Plate System are made of titanium alloy following ASTM F136.

Cervical Plate System is provided as non-sterile. The implants are intended for single-use only, while the instruments are reusable.

### **5.5 Indication for Use**

Cervical Plate System is intended for anterior interbody screw fixation from C2 to T1 and is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with:

- (1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
- (2) trauma (including fractures);
- (3) tumors;
- (4) deformity (defined as kyphosis, lordosis, or scoliosis);
- (5) pseudoarthrosis;
- (6) failed previous fusions.

### **5.6 Comparison of Technological Characteristics with the Predicate Device**

The rationale for substantial equivalence is based on consideration of the following characteristics:

**Regulatory Classification:** Same as the predicate devices

**Indications for Use:** Substantially equivalent (SE) to the predicate devices

**Materials:** Substantially equivalent (SE) to the predicate devices

**Design Features:** Substantially equivalent (SE) to the predicate devices

### **5.7 Non-Clinical Performance Data**

#### **5.7.1 Biocompatibility testing**

The biocompatibility evaluation for the Cervical Plate System was conducted in accordance with the FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

#### **5.7.2 Mechanical testing**

The following tests were performed (per *ASTM F1717 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model* on Anterior Cervical Spine Plate System to demonstrate substantially equivalent of safety and efficacy with the predicate device.

- Static compression bending test
- Static torsion test
- Dynamic compression bending test

### **5.8 Clinical Data**

No clinical performance data was provided to demonstrate substantial equivalence.

### **5.9 Conclusion**

The information provided within this premarket notification demonstrates that proposed device is determined to be substantially equivalent (SE) to the predicate device.